UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Mylan N.V. Securities Litigation	Case No. 1:16-CV-07926 (JPO) **MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS IN PART THE THIRD AMENDED COMPLAINT**

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TABLE OF ABBREVIATIONS

2016 Regulations	42 CFR § 447.509 (2016)
AC	Amended Class Action Complaint for Violation of Securities Laws (March 20, 2017) [Dkt. 39]
Class Period	February 21, 2012 to May 24, 2019, inclusive
Company	Mylan N.V. and/or Mylan Inc.
CW	Confidential Witness (described in TAC ¶ 148)
Defendants	Mylan N.V., Mylan Inc., Heather Bresch, Robert J. Coury, Paul B. Campbell, James Nesta, Kenneth S. Parks, John D. Sheehan
Defs.' Mem.	Memorandum of Law in Support of Defendants' Partial Motion to Dismiss [Dkt. 124]
DOJ	U.S. Department of Justice
Doxy DR	doxycycline hyclate delayed release
EpiPen	EpiPen Auto-Injector® and EpiPen Jr. Auto-Injector®
Individual Defendants	Heather Bresch, Robert J. Coury, Paul B. Campbell, Kenneth S. Parks, John D. Sheehan and Rajiv Malik
May 10, 2019 AG Action	*State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS
MDRP	Medicaid Drug Rebate Program
Motion	Defendants' Partial Motion to Dismiss the Third Amended Complaint
MTD Op. I	March 28, 2018 Opinion and Order [Dkt. No. 69]
MTD Op. II	March 29, 2019 Opinion and Order [Dkt. No. 102]
Mylan	Mylan N.V. and/or Mylan Inc.
Plaintiffs	Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd. and Dan Kleinerman
PSLRA	Private Securities Litigation Reform Act of 1995
RRA	Right Rebate Act of 2019 (42 U.S.C. §§ 1396r–8 et seq. (2019))
SAC	Second Amended Class Action Complaint for Violation of Securities Laws (July 6, 2018) [Dkt. 89]
Sanofi	Sanofi-Aventis S.A.
SOX	Sarbanes-Oxley Act of 2002
SEC	United States Securities and Exchange Commission
Section 10(b)	Securities Exchange Act, 15 U.S.C. § 78j(b)
Section 20(a)	Securities Exchange Act, 15 U.S.C. § 78t(a)
TAC	Third Amended Class Action Complaint for Violation of Securities Laws (June 17, 2019) [Dkt. No. 114]
Teva	Teva Pharmaceutical Industries Ltd.

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I. PRELIMINARY STATEMENT

The allegations of the TAC make clear that Defendants are guilty of extreme misconduct. Defendants were central participants in what is likely the largest cartel in this country's history—the TAC alleges that Defendants conspired with competitors in the generic drug industry to allocate the market and fix the price of virtually all of the generic drugs they sold. Defendants' conduct with respect to their only significant non-generic drug, the EpiPen, was just as abhorrent—Defendants cheated Medicaid out of hundreds of millions of dollars by misclassifying the EpiPen and inflated the price of the EpiPen by over 500% by pricing its primary competitor out of the market using an illegal rebate scheme. Defendants lied about all of this misconduct to investors for the better part of a decade.

This Court properly sustained the vast majority of the SAC. The TAC makes no changes to the allegations previously sustained by the Court. Rather, the TAC greatly expands the allegations in the SAC relating to Defendants' market allocation and price-fixing activity. The TAC makes clear that this anticompetitive conduct was not limited to a handful of drugs, but rather constituted Mylan's *modus operandi* in the generic drug market.

Defendants concede that the vast majority of the new allegations in the TAC are properly pleaded—Defendants concede that Plaintiffs have adequately pleaded that Defendants allocated the market for, and/or fixed the price of, 19 separate drugs.[1] Defendants' primary argument against the new allegations in the TAC is that Plaintiffs have failed fully to plead antitrust violations with respect to additional specific drugs beyond these 19. Defendants miss the thrust of the expanded allegations in the TAC. The TAC pleads that Defendants' market allocation and

[1] Defendants concede that Plaintiffs have adequately alleged that one or more of them allocated the markets for Doxy DR, Fenofibrate, Clonidine-TTS Patch, Tolterodine Extended Release, Capecitabine, and Valsartan HCTZ (the "Uncontested Market-Allocated Drugs"), and fixed the prices of Albuterol Sulfate, Benazepril, Clomipramine, Propranolol, Amiloride Hydrochloride, Doxazosin Mesylate, Ketorolac, Loperamide HCL, Levothyroxine Sodium, Methotrexate, Nadolol, Tizanidine, and Trifluoperazine HCL (the "Uncontested Price-Fixed Drugs").

price-fixing activity was so rampant that it affected virtually all of the generic drugs Mylan sold, and allegations with respect to 19 such drugs should be more than sufficient to support this broader allegation, which the Court should sustain.[2]

Unable to attack the vast majority of the allegations newly added in the TAC, Defendants focus their motion to dismiss instead on relitigating allegations previously sustained by this Court. The Court should decline this invitation to reconsider its prior opinions. *First*, Defendants argue that this Court should reverse its holding that certain statements by Mylan—statements that its classification of the EpiPen under the MDRP was subject to risk of error—were actionable. Defendants' argument that the recently passed RRA shows that the MDRP statute was ambiguous is meritless. Congress does not make rulings on ambiguity, and even if it did, Congress has never found that the MDRP statute was ambiguous. Even if it had, actions taken by Congress more than seven years after the alleged misstatements have no bearing on whether those statements were false or misleading when made. In any event, Defendants were well aware of how the MDRP statute applied to EpiPen because CMS repeatedly told Mylan directly that the EpiPen was misclassified.

Second, Defendants ask the Court for a second time to toss out critical allegations that Mylan was able to inflate the price of the EpiPen by over 500% by pricing its primary competitor out of the market using an illegal rebate scheme—allegations that make up one-third of this case. Here, Defendants cannot point even to a change in the law as an ostensible basis for reconsideration—the EpiPen antitrust allegations Defendants ask the Court to dismiss are identical to those in the SAC that the Court has sustained. The Court should sustain them again.

[2] Defendants appear to address the appropriateness of discovery with respect to drugs other than the 19 for which they concede that Plaintiffs have adequately pleaded an antitrust violation. (Defs.' Mem. at 14-15.) While discovery with respect to all generic drugs Mylan sold during the Class Period is warranted given the overwhelming likelihood that such discovery will lead to admissible evidence of widespread market allocation and price-fixing activity, the Court may resolve disputes over the scope of discovery requests when they arise.

Contrary to Defendants' arguments, Defendants were well aware of pricing decisions, and so would have had robust knowledge of the rebate pricing of the Company's most important product, the EpiPen. Likewise, Plaintiffs have pleaded loss causation with respect to these allegations more than adequately to survive a motion to dismiss (again).

Third, Defendants ask the Court to revisit its holding that Plaintiffs adequately pleaded price-fixing of Divalproex. Defendants argue that the parallel price movements of Divalproex during the Class Period are better explained by a ban on a supplier based in India. Defendants' argument fails for numerous reasons, not the least of which is that Defendants fail to provide any indication that the referenced supplier in India even manufactured Divalproex.

Defendants' remaining arguments are no more successful. Defendants argue that Plaintiffs have failed to allege that Defendant Nesta made any of the statements at issue, but such allegations are unnecessary to allege scheme liability for Nesta and Mylan. Defendants' argument that the Individual Defendants had compartmentalized knowledge that Mylan was involved in price-fixing and market allocation with respect to some drugs but not others strains credulity. Finally, Defendants' argument that the May 28, 2019 corrective disclosure, a UBS report, revealed no new facts to the market, is demonstrably wrong—as stated in its text, the report conveyed non-public information based on private conversations held by UBS.

For these reasons, the Court should deny Defendants' motion.

II. STATEMENT OF FACTS

In the TAC, Plaintiffs allege three categories of misconduct on the part of Mylan that make statements by Defendants to investors false and misleading: (1) Mylan knowingly misclassified the EpiPen for the purposes of the MDRP, (2) Mylan offered anticompetitive rebates on the EpiPen in order to eliminate competition and inflate the price of the EpiPen, and

(3) Mylan was a central participant in a massive cartel among generic drug companies that allocated the markets for, and fixed the prices of, generic drugs.

A. Mylan Knowingly Misclassified the EpiPen for the Purposes of the MDRP

The EpiPen® is a brand-name epinephrine auto-injector for the emergency treatment of anaphylaxis. (TAC ¶ 3). It is Mylan's most important product: sales of the EpiPen accounted for between 28% and 95% of Mylan's profits during the Class Period. (TAC ¶ 45.)

The MDRP is a government program associated with Medicaid under which a drug company may receive state Medicaid coverage for the manufacturer's drugs if the manufacturer rebates a portion of its sales to Medicaid. (TAC ¶¶ 53-55.) Under the MDRP, manufacturers are responsible for classifying their drugs as brand-name ("S" or "I") drugs or as generic ("N") drugs, and for rebating Medicaid's purchases of brand-name drugs at a rate of 23.1%, and generic drugs at a rate of 13%. (TAC ¶¶ 56-65.)

Classification for the purposes of the rebate is simple. (TAC ¶¶ 71-75.) As Mylan itself repeatedly explained in no uncertain terms in its 10-K filings throughout the Class Period:

> The required rebate [under the MDRP] is currently 13% of the [AMP] for sales of [] products marketed under ANDAs . . . . Sales of [] products marketed under NDAs require manufacturers to rebate . . . 23% . . . .

(TAC ¶ 76.) That is, under the MDRP, all drugs that are approved under NDAs must be classified as S or I drugs (and be subject to a 23% rebate), whereas all drugs that are approved under ANDAs must be classified as N drugs (and be subject to a 13% rebate). (TAC ¶ 65.) On at least two occasions since 2007, CMS issued clear guidance that this was the simple rule, and in both instances, CMS's statement of the rule constituted one paragraph. (TAC ¶¶ 60-61.)

Mylan consistently misclassified the EpiPen as a generic N drug. (TAC ¶¶ 69-77.) The EpiPen is marketed under an NDA, and under the simple rule for classification of drugs under the MDRP that Mylan itself repeatedly stated in its SEC filings, Mylan was required to classify

the EpiPen as an S or I drug and to give Medicaid the greater rebate applicable to brand-name drugs of approximately 23% of AMP. (TAC ¶¶ 67, 71-76.)

Mylan clearly knew the EpiPen was misclassified. (TAC ¶¶ 69-87.) *CMS itself*, the agency responsible in the first instance for interpreting and implementing the 1990 Act, *expressly told Mylan* prior to the start of the Class Period that its classification of the EpiPen as a generic N drug was incorrect. (TAC ¶ 77.) On March 16, 2009, the HHS IG provided CMS with a list of eight drugs, including the EpiPen, that it had determined to be misclassified. (*Id.*) Subsequently, CMS notified Mylan about the misclassification: as CMS stated to a member of Congress, "CMS has, on multiple occasions . . . expressly told Mylan that [the EpiPen] is incorrectly classified." (*Id.*) Senator Grassley recently confirmed that "CMS provided records to the [Senate Judiciary] Committee that show CMS told Mylan on several occasions that the EpiPen was misclassified, yet Mylan failed to correct the classification," and that Mylan had "overcharged the taxpayers *for years* with the knowledge EpiPen was misclassified." (*Id.*)

Furthermore, in November 2014, Mylan received a subpoena from the DOJ as part of the DOJ's investigation into "whether EpiPen Auto-Injector was properly classified with [CMS]." (TAC ¶ 84.) Accordingly, by November 2014 at the very latest, even the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan's classification of the EpiPen for the purposes of the MDRP was likely incorrect. (*Id.*)

B. Mylan Engaged in Anticompetitive Conduct To Allow It To Inflate the Price of the EpiPen

From 2013 to 2015, commercial insurance companies and pharmaceutical benefit managers (who manage the pharmacy benefits of group health plan sponsors) (together "third-party payors") accounted for 71% of the market for epinephrine autoinjectors in the U.S. (TAC ¶ 107.) Given the dominance of third-party payors in the market for epinephrine autoinjectors, a

drug company seeking to enter this market must have its drug included on the lists of drugs for reimbursement maintained by third-party payors (their "formularies"). (TAC ¶ 108.) These formularies are tiered according to required co-payments, so consumers are incentivized to select drugs on tiers with lower co-pays. (*Id.*) If a drug is wholly excluded from a third-party payor's formulary, the drug is often too expensive for patients to purchase. (*Id.*)

Mylan has monopoly power in the market for epinephrine autoinjectors. (TAC ¶ 106.) Since Mylan acquired EpiPen, the product has accounted for more than 90% of the U.S. market for these devices, and Mylan has increased the price for EpiPen more than 500%. (*Id.*)

In January 2013, the drug company Sanofi-Aventis U.S. LLC ("Sanofi") introduced an epinephrine autoinjector, the Auvi-Q, to compete with the EpiPen and sold it for roughly the same price as the EpiPen's. (TAC ¶ 109.) The Auvi-Q was a superior autoinjector to the EpiPen in several ways. (*Id.*) The device sold successfully its first few months on the market. (*Id.*)

Mylan responded to this new competitive threat by excluding the Auvi-Q from the market. (TAC ¶ 110.) Shortly following the release of the Auvi-Q, Mylan began offering massive rebates to third-party payors on the express condition that the third-party payors not include the Auvi-Q in their formularies. (*Id.*) These highly unusual rebates amounted to 30% or more of the price that Mylan otherwise would have offered. (*Id.*) Mylan had no legitimate business reason to offer these unprecedented rebates conditioned expressly on excluding the Auvi-Q from the market; they were offered to block that device from competing. (*Id.*)

Due to Mylan's price increases, the net, after-rebate price of EpiPen actually *rose* after Mylan began its exclusionary rebates. (TAC ¶ 111.) Mylan offered no rebates when it sold the EpiPen in 2012 for around $200, but when Mylan began to offer a 30% rebate on the EpiPen and increased its price to around $300 by 2014, the net price of EpiPen rose to $210. (*Id.*)

Sanofi was unable to offer massive rebates on Auvi-Q in line with those offered by Mylan for EpiPen. (TAC ¶ 112.) Given Mylan's monopoly market share, the opportunity cost to third-party payors of foregoing Mylan's rebates was very significant. (*Id.*) As the Auvi-Q held only around 10% of the market, Sanofi would have had to offer rebates far greater than Mylan's (and far in excess of its revenues from Auvi-Q) in order to match the total value of Mylan's rebates that the payor would have to forego in order to buy the Auvi-Q. (*Id.*)

Mylan successfully blocked Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine autoinjectors. (TAC ¶ 113.) In 2014, Mylan's anticompetitive rebates blocked Auvi-Q from about 45% of the individuals covered by commercial payors. (*Id.*) In certain states in which third-party payors that did not cover Auvi-Q due to Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market. (*Id.*) Moreover, the decisions of third-party payors not to cover Auvi-Q also led doctors to decline to prescribe Sanofi's product, which led to Mylan's effectively excluding the Auvi-Q from well over 50% of the national market for epinephrine autoinjectors. (TAC ¶ 114.)

When Mylan's conditional rebates blocking Auvi-Q took effect around December 2013, Auvi-Q's U.S. commercial payor market share in the market for epinephrine autoinjectors dropped by nearly 50%, from about 13% to 7% by early 2014. (TAC ¶ 116.) By April 2014, Auvi-Q's national market share across all payors had slid from 11% in mid-2013 to only 6%, while its market share in 2014 had been projected by Sanofi to exceed 20%. (*Id.*) By October 2015, Auvi-Q's national market share was less than half of what Sanofi had projected. (*Id.*)

Ultimately, in October 2015, Sanofi was forced not to relaunch Auvi-Q due to the impact of Mylan's anticompetitive rebates. (TAC ¶ 119.) In April 2017, Sanofi sued Mylan for

antitrust violations, and on December 21, 2017, the district court held that Sanofi had adequately pleaded antitrust claims based on substantially the same facts as those alleged here.[3]

C. Mylan Was a Leader of an Unprecedented Cartel Among Generic Drug Companies

During the Class Period, Mylan was a central participant in a massive cartel that allocated the market for, and fixed the prices of, virtually all of the generic drugs sold in this country. Mylan repeatedly misled investors about its central role in this cartel. Mylan and its co-conspirators' anticompetitive activity was so widespread that it was the standard procedure by which these companies operated in the marketplace: each company agreed not compete with one another and was entitled to its "fair share" of the market. (TAC ¶ 25.) The companies agreed to "play nice in the sandbox." (*Id.*) These rules about "fair share" applied equally to price increases. (TAC ¶ 134.) As long as all co-conspirators were playing fair, and the competitors believed that they had their "fair share," they would not seek to compete or take advantage of each other's price increase by bidding a lower price to take business. (*Id.*) Mylan's market allocation and price-fixing activity were two sides of the same coin—both activities were part of the same conspiracy with generic drug manufacturers to manipulate prices of generic drugs.

1. Mylan Conspired with Other Drug Companies To Allocate the Market for Various Generic Drugs

During the Class Period, Mylan misled investors about its scheme to allocate the market between itself and competitors for virtually every generic drug that it marketed by agreeing with competitors not to compete for certain businesses the competitors targeted in exchange for their reciprocal agreement not to compete for customers Mylan targeted. (TAC ¶ 121-41.) The TAC alleges that Mylan illegally allocated the market for at least the following drugs: Doxy DR;

[3] *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, MDL No. 2785, 2017 U.S. Dist. LEXIS 209710, at **77-78 (D. Kan. Dec. 21, 2017).

Fenofibrate; Clonidine-TTS Patch; Tolterodine Extended Release; Capecitabine; Enalapril; and Valsartan HCTZ. (TAC ¶¶ 151-79, 180-91, 192-206, 207-19, 220-33, 234-50, 251-58)

2. Mylan Entered into Price Fixing Agreements with Competitors To Fix the Price of Generic Drugs

Beginning in or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained price fixing agreements with the other major participants in the market for generic drugs. (TAC ¶¶ 259-422.) For years prior to 2013, prices for the generic drugs had remained stable. (TAC ¶¶ 262, 268, 274, 280, 286, 296, 302, 308, 314, 320, 326, 332, 341, 347.) Immediately or soon after Defendants entered these agreements, Mylan and all other industry participants increased the prices of the Fixed-Price Drugs astronomically, in each case by hundreds or thousands of percentage points. (TAC ¶¶ 259-422.) Mylan and its co-conspirators had numerous opportunities to meet to plan their conspiracy, at industry meetings, trade shows and private "industry dinners" among high-level executives. (TAC ¶¶ 396-400.)

Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by Congress and federal and state antitrust regulators. (TAC ¶¶ 409-22.) Most recently, on May 10, 2019, the attorneys general of over forty states filed a new antitrust action against Mylan and other generic drug companies in the U.S. District Court for the District of Connecticut. *See State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (the "May 10, 2019 AG Action"). (TAC ¶ 422.) The complaint alleges an industry-wide conspiracy in which Mylan was a central participant; it details how executives at Mylan expressly agreed with other drug companies in specified calls and other communications to allocate the market for, and to fix the prices of, generic drugs—activity involving virtually the entire generic drug industry. (*Id.*)

D. In August 2016, January 30, 2017 and May 28, 2019, Among Other Dates, Mylan's Stock Dropped When the Truths Concealed by Its Conduct Were Partially Revealed and Risks Materialized

While Plaintiffs losses were caused on numerous dates, those relevant to the present Motion are the stock drops that occurred in August 2016 and on January 30, 2017 and May 28, 2019. In late August 2016, a series of news articles highlighted Mylan's 500% increase in the price of EpiPen. (TAC ¶¶ 549-54.) The same week, U.S. Senators called for government investigations, including an FTC investigation, into Mylan's conduct and whether Mylan had violated antitrust laws to be able to raise the price of this drug so massively. (TAC ¶ 552.) Upon these revelations, Mylan's stock price dropped precipitously $6.17 or 12.51% between August 19 and August 24, 2016. (TAC ¶ 554.) Likewise, on January 30, 2017, Bloomberg News reported that Mylan had received a request for information from the FTC regarding whether Mylan had engaged in anticompetitive activity relating to the EpiPen. On this news, Mylan shares fell $0.32, or 0.87% to close at $36.34 on January 30, 2017.

On May 28, 2019, UBS published a report titled, "Mylan Inc., Expanded Alleged Price Fixing Creates Another Overhang—Reiterate Neutral; TP to $23." (TAC ¶ 576.) In this report, UBS provided details regarding the potential exposure the Company faced in the 2017 and 2019 antitrust suits by the state attorneys general. (*Id.*) On this news, Mylan shares fell $1.11, or 5.85%, to close at $17.87 on May 28, 2019. (*Id.*)

E. Procedural History

In its March 28, 2018 Opinion, the Court sustained the majority of the allegations in the Amended Complaint. The Court found that Plaintiffs had adequately pleaded that Defendants had repeatedly misled investors for years about their classification of the EpiPen for the purposes of the MDRP. (MTD Op. I at 15-20, 24-25.) The Court also found that Plaintiffs had adequately

pleaded that Defendants had colluded with competitors to fix the price of five generic drugs and had misleadingly concealed that activity from investors. (*Id*. at 11-15, 30-34.)

In its March 29, 2019 Opinion, this Court issued an Opinion and Order granting in part, and denying in part the SAC. (Dkt. No. 102.) In this Opinion, the Court sustained Plaintiffs' allegations that Mylan offered anticompetitive rebates on EpiPen to third-party payors in order to price competitors out of the market for epinephrine autoinjectors, MTD Op. II at 11-12, and that Defendant Malik had knowingly conspired with competitors to allocate the market for the generic drug Doxy DR, *id*. at 22-24. The Court also permitted allegations of an additional 6% stock drop relating to Mylan's anticompetitive conduct to proceed. (*Id*. at 15-18.)

On June 17, 2019, Plaintiffs filed the TAC adding new allegations, as stated in the May 10, 2019 AG Action, of anticompetitive conduct on the part of Mylan and other generic drug companies with respect to numerous generic drugs (*see Connecticut v. Teva Pharma. USA, Inc*., No. 3:19-cv-00710 (MPS) (D. Conn.)). (Dkt. No. 114.) The TAC also added Defendant Nesta and extended the Class Period. (*Id*.) On July 31, 2019, Defendants moved to dismiss the TAC. (Dkt. No. 124.) Defendants' Motion does not contest the majority of the TAC.[4]

[4] Specifically, Defendants do not contest at least the following elements of Plaintiffs' claims: (1) the falsity, materiality and scienter elements of Plaintiffs' Section 10b and Rule 10b-5 claims against Mylan based on the following categories of misstatements first defined in MTD Op. I at 5, 19 (the "Uncontested Misstatements"): (a) "Statements Explaining Income," (b) "Statements Explaining the Market," (c) "Statements of Rebate Rates," (d) statements that "a governmental authority may take a . . . contrary" position and that Mylan "could [be] subject[ed] . . . to investigation," to the extent these misstatements are grounded in allegations of misrepresented or omitted truths including: (i) Mylan's misclassification of the EpiPen for the purposes of the MDRP, (ii) the rebate rate for EpiPen, (iii) the existence of government investigations into Mylan's misclassification of the EpiPen (together with (i) and (ii), the "Uncontested EpiPen Misconduct"), (iv) Mylan's violations of antitrust law by allocating the markets for the Uncontested Market-Allocated Drugs, and (v) Mylan's violations of antitrust law by fixing the prices of the Uncontested Price-Fixed Drugs; (2) the falsity, materiality and scienter elements of Plaintiffs' Section 10b and Rule 10b-5 claims against Defendant Malik based on the Uncontested Misstatements, to the extent grounded in allegations of violations of antitrust law by allocating the markets for Doxy DR; (3) the falsity, materiality and scienter elements of Plaintiffs' Section 10b and Rule 10b-5 claims against Defendants Bresch, Coury, Campbell, Parks and Sheehan based on the Uncontested Misstatements, to the extent grounded in allegations of the Uncontested EpiPen Misconduct and violations of antitrust law by fixing the prices of the Uncontested Price-Fixed Drugs; (4) all elements of Plaintiffs Section 20(A) claims against the Individual Defendants to the extent Plaintiffs' Section 10b and Rule 10b-5 claims against them are uncontested; (5) loss causation for all claims for all alleged corrective disclosure dates other than May 28, 2019.

III. ARGUMENT: THIS COURT CORRECTLY HELD THAT MYLAN'S STATEMENTS OF RISKS OF ERRORS WERE ACTIONABLE

As this Court has held, Plaintiffs have adequately pleaded that Mylan's statements that its rebate calculation for EpiPen was subject to risk of error ("Statements of Risk") were misleading to investors. (MTD Op. I at 20.) Mylan's warnings to investors that its rebate calculation for the EpiPen under the MDRP "*could be wrong* . . . impl[ied] that the rebate calculation *could also be correct*." (*Id*.) "If Mylan knew for certain that the EpiPen was misclassified," and that the rebate calculation therefore was not correct, "then warning about the 'risk of errors' [in the rebate calculation] could have misled a reasonable investor as to Mylan's then-existing knowledge" that the rebate calculation was incorrect. (*Id*.)

As this Court also has held, Plaintiffs have adequately pleaded that Mylan knew the EpiPen was misclassified and that its rebate calculation was therefore incorrect. (*Id*. at 25-26.) The Court found that "[t]he most important . . . piece[] of evidence" that Mylan knew the EpiPen was misclassified for the purposes of the MDRP was "the allegation that CMS 'repeatedly informed Mylan that Mylan was misclassifying the EpiPen for the purposes of the MDRP.'" (*Id*.) The Court reasoned that "the CMS communications reflected a final determination that Mylan had incorrectly classified EpiPen." (*Id*.) The Court further found that Plaintiffs' allegations regarding "the individual Defendants' high-level positions at Mylan, the importance of the EpiPen to Mylan's business, the individual Defendants' signed certifications . . . , and receipt of the DOJ subpoena" all "bolster[ed] the inference of scienter." (*Id.* at 26.) The Court noted that "whether the individual Defendants had knowledge of such misclassification is appropriately the subject of discovery." (*Id.*)

In their Motion, Defendants ask the Court to reconsider these holdings.[5] (Defs.' Mem. at 8-10.) Defendants argue that in passing the RRA, Congress clarified the MDRP statute, so the original statute must have been ambiguous. (*Id.*) As the original statute was ambiguous, according to Defendants, Defendants' interpretation could not have been wrong, their Statements of Risk of misclassification could not have been misleading, and Defendants could not have known that their interpretation of the statute was wrong. (*Id.* at 8-9.)

As an initial matter, Defendants' request that the Court read the RRA as exculpatory of Mylan is perverse. The RRA was passed expressly to prevent Mylan from exploiting HHS's inability to punish Mylan for its misclassification of the EpiPen. Members of Congress stated:

> The Right Rebate Act of 2019 . . . [c]loses the loophole that Mylan, and others, exploited by providing authority to the Secretary of HHS to reclassify drugs, impose civil monetary penalties, and recover incorrect rebate payments. [. . .] Overall, the legislation will prevent the EpiPen fiasco from happening again.[6]

That Defendants now argue that the RRA somehow excuses their having exploited the loophole the RRA was designed to close, the loophole that allowed them to get away for years with misclassifying the EpiPen and misleading investors about it, is jaw-dropping.

Defendants' request for reconsideration is meritless. *First*, determination of whether a statutory provision is ambiguous, like all exercises in statutory interpretation, is a judicial rather than a legislative function. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is.").

[5] "The law of the case doctrine commands that 'when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case' unless 'cogent and compelling reasons militate otherwise.' [. . .] '[C]ogent' or 'compelling' reasons includ[e] an intervening change in law, availability of new evidence, or 'the need to correct a clear error or prevent manifest injustice.'" *Johnson v. Holder*, 564 F.3d 95, 99-100 (2d Cir. 2009) (citations omitted); *see In re Initial Pub. Offering Sec. Litig.*, 544 F. Supp. 2d 277, 284 (S.D.N.Y. 2008) ("The law of the case doctrine generally forecloses relitigation of issues expressly or impliedly decided earlier in the proceeding."). Here, no relevant change in law, new evidence, or clear error support the Court's upending its prior rulings. The Court should not permit Defendants to use the amendment process as an excuse to relitigate those parts of the Court's prior rulings with which they disagree.

[6] Senate Finance Committee, *The Right Rebate Act of 2019* (Apr. 2, 2019), https://www.finance.senate.gov/imo/media/doc/Right%20Rebate%20Act%20of%202019%20One-pager.pdf

Congress's opinion on the ambiguity of a statute passed by a prior Congress has no more legal relevance to a Court interpreting that statute than a layperson's, and Defendants fail to cite any authority to the contrary. *Second*, even if Congress's opinion, years after the misrepresentations at issue were made, about ambiguity in former statutory language, were somehow relevant (it is not), this Congress made no statement or finding that the statute at issue was ambiguous—Congress merely changed the phrasing of the statute. Defendants' implicit premise that any change to the wording of a statutory provision indicates that the prior provision was ambiguous is wrong—rephrasing of a provision does not imply that the provision previously had more than one reasonable interpretation. *See United States. v. O'Brien*, 560 U.S. 218, 231-34 (2010) (court will not presume that rephrasing of statute caused substantive change in meaning of statute unless there is indication that Congress intended to make substantive change); *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 136 (2008) (same); *Keene Corp. v. United States*, 508 U.S. 200, 208-09 (1993) (same). *Third*, and in any event, even if the statute had been ambiguous (it was not), the application of the statute to EpiPen was always crystal clear to Mylan. As the Court correctly has emphasized, CMS, the government entity responsible for interpreting and administering the MDRP, "repeatedly informed Mylan that Mylan was misclassifying the EpiPen for the purposes of the MDRP."[7] MTD Op. I at 25-26.

IV. ARGUMENT: THIS COURT CORRECTLY HELD THAT PLAINTIFFS' CLAIMS BASED ON MYLAN'S ANTICOMPETITVE REBATES FOR EPIPEN ARE ACTIONABLE

[7] Moreover, as if being informed directly by CMS were not enough, as explained in the TAC, the MDRP statute and CMS guidance always applied straightforwardly to require that the EpiPen, which was marketed under an NDA, was to be classified as an S or I drug. (TAC ¶¶ 60-75.) Defendants argue that an exception existed for "non-original" NDAs, but that "narrow" exception from the 2016 Regulations was the only exception to the rule that all NDAs were to be classified as an S or I drug and manifestly did not apply to the EpiPen; for the purposes of the classification of the EpiPen, all that was relevant about the narrow exception was that it never applied to drugs, like the EpiPen, "that received patent protection." (TAC ¶ 63.) Notably, Mylan to date has yet to offer any argument for why the EpiPen properly should have been classified as a generic drug under the MDRP—there is none.

A. Defendants Knew About Mylan's Anticompetitive Rebates

As this Court already has ruled, the TAC adequately alleges Defendants' scienter with respect to Mylan's anticompetitive rebates for EpiPen.[8] (MTD Op. II at 11-12, 27.) In the Second Circuit, a strong inference of scienter "can be established by alleging facts to show . . . strong circumstantial evidence of conscious misbehavior or recklessness." *ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009); *Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 868, 585 (S.D.N.Y. 2016). Conscious misbehavior encompasses, among other things, "deliberate illegal behavior," *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). Recklessness with respect to an omission is adequately pleaded where the "plaintiff has pleaded facts demonstrating that [the defendant] had access to information indicating that [the omission] was [misleading]." *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 456 (S.D.N.Y. 2005) (citations omitted).

Defendants were well aware of the massive rebates that the Company offered to third-party payors contingent on their excluding Sanofi from the market for epinephrine autoinjectors. As the Court already has held, the Complaint adequately alleges that Mylan's CEO and CFO "certainly had access to, and actively participated in, pricing decisions." (MTD Op. I at 34.) As CW makes clear, "pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives," and "the CEO and CFO . . . reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs." (TAC ¶¶ 149, 586.) When it came to price,

[8] This Court already has rejected Defendants' argument that Plaintiffs' claims based on Mylan's anticompetitive rebates for EpiPen should be dismissed for failure to allege scienter. (MTD Op. II at 11 & n.4, 12, 27.) In their motion to dismiss the SAC, Defendants argued, "Plaintiffs . . . fail to allege Defendants acted with scienter with respect to these claims, which provides an additional, independent reason to dismiss Plaintiffs' claims that Mylan allegedly failed to disclose the EpiPen rebates." (Dkt. No. 96 at 8-9.) In response, Plaintiffs explained in detail how the SAC properly alleged scienter. (*See* Dkt. No. 100 at 17-18.) Defendants failed even to mention scienter in their reply, and so conceded that scienter with respect to Mylan's anticompetitive rebates for EpiPen had adequately been pleaded. (*See* Dkt. No. 100.) The Court noted that Defendants had failed to argue that scienter had not adequately been pleaded, and accepted Defendants' concession that scienter had adequately been pleaded by permitting Plaintiffs' claims premised on Defendants' scienter to proceed. (MTD Op. II at 27.) The Court was correct.

"[e]verything went up through the top." (*Id.*) Accordingly, Mylan's top executives, including the Individual Defendants, knew about, or at a minimum recklessly disregarded, the massive rebates Mylan offered to third-party payors on purchases of Mylan's key drug, the EpiPen.

Moreover, this Court already has held that Plaintiffs have pleaded adequately that Defendants violated antitrust laws through their use of these exclusionary rebates. (MTD Op. II at 11-12.) Even standing alone, these pleadings are sufficient to allege conscious misbehavior, and therewith scienter, with respect to this anticompetitive activity. *See Novak*, 216 F.3d at 308. Additional allegations cement this conclusion. That Mylan's sales of EpiPen are part of its core operations (TAC ¶ 45) "buttress the allegations of scienter." *In re Salix Pharm., Ltd.*, No. 14-cv-8925, 2016 U.S. Dist. LEXIS 54202, at *50 (S.D.N.Y. Apr. 22, 2016). Defendants' SOX certifications likewise support an inference of scienter in the Court's holistic analysis. *See, e.g.*, *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 491 (S.D.N.Y. 2004).

Defendants ask the Court to reconsider its ruling that scienter has adequately been pleaded. (Defs.' Mem. at 10.) Defendants argue that the TAC relies solely on allegations that the EpiPen was part of Mylan's core operations. (*Id.*) As explained above, that is wrong—the TAC alleges that Defendants were well aware of pricing decisions, and so would have been keenly aware of the pricing and rebate strategy for the Company's primary drug, the EpiPen. (TAC ¶¶ 149, 586.)

Defendants also argue that Plaintiffs have failed to plead that Defendants knew the rebates adversely affected competition. (Defs.' Mem. at 12.) While such a pleading is unnecessary, Defendants are wrong—Plaintiffs plead that Defendants devised the rebates specifically to force Sanofi out of the market in order to inflate the price of the EpiPen. (TAC ¶¶ 104, 110, 119.) It is implausible that Defendants did not know that their rebates adversely

affected competition—the purpose and effect of the rebates was to prevent a competitor from entering the market. (*Id.*) Moreover, as this Court has acknowledged, the TAC adequately alleges that there were no procompetitive effects of the rebates because the rebates caused the net price of the EpiPen to increase. (MTD Op. II at 12 (citing TAC ¶¶ 100, 105).) Defendants knew the pricing of the EpiPen, (TAC ¶¶ 149, 586), and it is implausible that Defendants did not know that rebates that *increased* the net price of this product had no net procompetitive effects.

B. Materialization of the Risks of Mylan's Anticompetitive Pricing of EpiPen Caused Losses to Plaintiffs

Plaintiffs have adequately pleaded that Defendants' misrepresentations concerning Mylan's anticompetitive rebates for EpiPen caused them losses when the risks of that anticompetitive conduct materialized. Indeed, the Court already has sustained twice the alleged loss causation dates relating to Mylan's anticompetitive rebates, August 19-24, 2016 and January 30, 2017, all of which were alleged in the First Amended Complaint. (MTD Op. I at 35-36.)

The requirement of loss causation, "is not intended to impose a great burden on a plaintiff," as Plaintiffs need only meet Rule 8 notice pleading standards, which are met by "provid[ing] a defendant with some indication of the loss and the causal connection that the plaintiff has in mind . . . ." MTD Op. I at 35-36 (quoting *Fin. Guar. Ins. Co. v. Putnam Advisory Co.*, 783 F.3d 395, 404 (2d Cir. 2015)); *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). In the Second Circuit, no particular type of disclosure is required to show loss causation:

> [While] a plaintiff can establish loss causation either by showing a 'materialization of risk' or by identifying a 'corrective disclosure' that reveals the truth behind the alleged fraud, our past holdings do not suggest that 'corrective disclosure' and 'materialization of risk' create fundamentally different pathways for proving loss causation, such that a specific corrective disclosure is the only method by which a plaintiff may prove losses resulting from the revelation of the truth. Indeed, . . .'to establish loss causation, [plaintiffs must show that a] . . . misstatement or omission concealed *something* from the market that, when disclosed, negatively affected the value of the security.'

In re Vivendi, S.A. Sec. Litig., 838 F.3d 223, 261-62 (2d Cir. 2016) (citations omitted). A misrepresentation is cause of an investment loss "if the risk that caused the loss was within the zone of risk concealed by the misrepresentations . . . ." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d. Cir. Jan 20, 2005). "Put more simply, proof of loss causation requires demonstrating that 'the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered.'" *In re Vivendi*, 838 F.3d at 261 (quoting *Suez Equity Inv'rs, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 95 (2d Cir. 2001)). It is well established that news of an "investigation into a particular business practice can be sufficient to allege loss causation with respect to alleged misstatements regarding that practice." *See In re New Oriental Educ. & Tech. Grp. Sec. Litig.*, 988 F. Supp. 2d 406, 428 (S.D.N.Y. 2013); *Cohen v. Kitov Pharm. Holdings*, Ltd., 2018 U.S. Dist. LEXIS 45676, at *19-20 (S.D.N.Y. Mar. 20, 2018) (collecting cases).

The TAC alleges:

> In late August 2016, a news article detailed how Mylan had increased the price of the EpiPen over 500%, revealing the effects of Mylan's anticompetitive conduct and causing public outcry. U.S. Congresspersons then called on Congress and the FTC to investigate Mylan for anticompetitive conduct relating to the EpiPen. Upon this news and other related revelations, Mylan stock fell $6.17, or 12.51% between August 19 and August 24, 2016. When the FTC announced on January 30, 2017 that it was investigating Mylan, Mylan's stock fell even further.

(TAC ¶ 20.) The TAC further alleges that "[o]n this news . . . , risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell . . . ." (TAC ¶ 554.)

These allegations "provide [] defendant[s] with some indication of the loss and the causal connection that the plaintiff has in mind." (MTD Op. I at 35-36.) Mylan's anticompetitive activity that inflated the price of EpiPen was partially revealed through the announcement of investigations into whether Mylan was acting anticompetitively in marketing the EpiPen. (TAC ¶ 554.) *See, e.g.*, *In re New Oriental*, 988 F. Supp. 2d at 428. Moreover, in misleading investors

about the fact that it was engaging in anticompetitive conduct to inflate the price of EpiPen astronomically, Mylan concealed the risks of a public outcry over the pricing of EpiPen and of investigation into the Company's anticompetitive conduct. (TAC ¶¶ 20, 105, 120.)

Defendants argue that Plaintiffs have failed to plead loss causation because they "do not identify a single corrective disclosure connected to Mylan's agreements with PBMs . . . ." (Defs.' Mem. at 13.) As explained above, Plaintiffs allege multiple such disclosures (all of which have previously been sustained twice by the Court (MTD Op. I at 35-36)).

V. THE COURT CORRECTLY HELD THAT PLAINTIFFS HAVE ADEQUATELY PLEADED DEFENDANTS' PRICE-FIXING OF DIVALPROEX

As this Court correctly has held, Plaintiffs adequately have pleaded that Defendants conspired to fix the price of Divalproex. (MTD Op. I at 31.) The Court held that the Complaint "identifies parallel price movements for [Divalproex], characterized by a sharp spike over the course of several months, and additional factors that tend to indicate conscious agreement to raise prices. (MTD Op. I at 31-32 (citing SAC ¶¶ 131, 137, 149, 155).) Defendants failed even to mention Divalproex in their motion to dismiss the SAC.

Defendants now argue that Mylan's price increases for Divalproex in parallel with competition are better explained by a purported supply shortage that occurred when Wockhardt (which Defendants claim to be a major supplier of Divalproex) was forced to exit the market due to an import ban on one of its manufacturing facilities in India. (Defs.' Mem. at 16.) To support this argument, Defendants attach an "Import Alert" purportedly published by the FDA. (*See* Dkt. No. 125 (Decl. of R. Leraris, Ex. 1 ("Exhibit 1")).)

Defendants' argument fails at every turn. *First*, even if Exhibit 1 is a public record of which the Court may take judicial notice (which Plaintiffs do not concede), the Court may take judicial notice of this record only "to determine what statements the documents contain, not for

the truth of the matters asserted." *Becker v. Cephalon, Inc*., No. 14 Civ. 3864 (NSR), 2015 U.S. Dist. LEXIS 123670, at *7 (S.D.N.Y. Sept. 15, 2015) (quoting *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 412 (S.D.N.Y. 2011)) (cited by Defendants). Defendants' argument depends entirely on the truth of the matter they claim is evidenced by the record (*i.e.*, a supply shortage), so Defendants' argument lacks support. *Second*, even if the Court could take judicial notice of the truth of the content of Exhibit 1 (it cannot), Exhibit 1 does not evidence a supply shortage of Divalproex—in fact, the document makes no mention of Divalproex, and Defendants offer no reason for the Court to accept their assertion that Wockhardt was a supplier of Divalproex, let alone a "major" supplier. *Third*, Defendants likewise offer no basis for the Court to believe that the market was materially reliant on Wockhardt for Divalproex, such that a ban of one of Wockhardt's manufacturing facilities in India would cause the price of Divalproex to increase six-fold. Finally, the ban on the Wockhardt manufacturing facility in India on which Defendants rely was announced in May 2013, while the AC alleges that the price spike for at least one of the common dosages of Divalproex began two months before the purported ban began, in March 2013, and the most significant spike in price occurred five months after the purported ban began, in September 2013. (TAC ¶ 283.) Accordingly, even assuming as true all the facts Defendants wrongfully ask the Court to assume, the price movements alleged in the TAC cannot be explained away by a May 2013 ban.

VI. PLAINTIFFS PROPERLY PLEAD LIABILITY OF THE INDIVIUDAL DEFENDANTS

A. Plaintiffs Properly Plead "Scheme Liability" for Jim Nesta and Mylan

Under the allegations of the TAC, Defendants, including Jim Nesta, are liable under Sections (a) and (c) of Rule 10b-5, which provide for "scheme liability." To allege scheme liability, a plaintiff must plead "(1) that the defendant committed a deceptive or manipulative act,

(2) in furtherance of the alleged scheme to defraud, (3) with scienter, and (4) reliance." *Menaldi*, 164 F. Supp. 3d at 577 (quoting *In re Alstom, SA Sec. Litig.*, 406 F. Supp. 2d at 474). The reliance element may be shown through the *Basic* and *Affiliated Ute* presumptions. *See Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 159 (2008) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 243 (1988); *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 154 (1972).

The allegations against Defendants Nesta and Mylan straightforwardly satisfy these criteria. Defendant Nesta was "a central player in Mylan's market allocation and price-fixing scheme," and as Nesta was only one reporting level removed from the CEO, he was sufficiently senior at Mylan that his knowledge and actions may be imputed to the corporation. (TAC ¶ 183.) *See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015). In carrying out their market allocation and price-fixing activity—inherently deceptive and manipulative activity—Nesta and Mylan committed numerous deceptive and manipulative acts. For example, Mylan and Jim Nesta's acts of submitting cover bids to customers—bids that were meant to appear as genuine bids among competitors but were in fact intentionally uncompetitive—were deceptive acts, and these acts were independent of the false and misleading statements Defendants made to investors concealing the scheme. (TAC ¶ 183.) Moreover, these deceptive acts were done in furtherance of Defendants' scheme to allocate the markets for generic drugs and ultimately to defraud investors. *Id*. Nesta knowingly participated in these acts. (*See, e.g.*, TAC ¶ 183, 187, 198, 206, 213.) Finally, reliance is satisfied under the *Basic* and *Affiliated Ute* presumptions because Mylan stock traded in an efficient market and Mylan repeatedly omitted facts in furtherance of its scheme that it was under a duty to disclose. *Stoneridge*, 552 U.S. at 159. Moreover, Plaintiffs, like other investors, relied on Mylan and

Nesta's deceptive acts because those acts "made it 'necessary or inevitable' that falsehoods on the part of [the Company] would result." *In re Eletrobras Sec. Litig.*, 245 F. Supp. 3d 450, 472 (S.D.N.Y. 2017) (quoting *Stoneridge*, 552 U.S. at 152-53, 159, 160-61). For example, Mylan and Nesta's deceptive acts made necessary or inevitable that Mylan would misrepresent its sources of income when Mylan explained its business to investors. (*See, e.g.*, TAC 469-74.)

Defendants argue that Plaintiffs' Rule 10b-5 claim against Nesta should be dismissed because the TAC does not allege that Nesta made any of the misstatements at issue. (Defs.' Mem. at 20.) Defendants ignore that the TAC alleges that Nesta and Mylan are liable under Sections (a) and (c) of Rule 10b-5, (TAC ¶ 612), and Nesta's liability under these Sections does not require that he have made any misstatements. *See SEC v. Knight*, 694 F. App'x 853, 856 (2d Cir. 2017) (citing *Janus Capital Grp., Inc. v. First Derivative Traders*, 564 U.S. 135 (2011)); *see also, e.g.*, *IBEW Local 90 Pension Fund v. Deutsche Bank AG*, No. 11 Civ. 4209 (KBF), 2013 U.S. Dist. LEXIS 43774, at *25 (S.D.N.Y. Mar. 27, 2013) (scheme liability adequately pleaded); *In re Galena Biopharma, Inc. Sec. Litig.*, 117 F. Supp. 3d 1145, 1199 (D. Or. 2015) (same).

B. The Individual Defendants Knew, or Were Severely Reckless in Not Knowing, About the Company's Rampant Price-Fixing and Market Allocation Activity

The TAC adequately pleads scienter for the Individual Defendants with respect to the Company's market allocation and price-fixing activity. Defendants do not dispute this Court's holding (MTD Op. I at 33-35) that the TAC adequately alleges that Defendants Bresch, Coury, Campbell, Parks and Sheehan knew about Mylan's price-fixing activity, but Defendants now argue that their scienter has not been pleaded with respect to Mylan's market allocation activity. (Defs.' Mem. at 22.) Defendants do not dispute this Court's holding (MTD Op. II at 24) that the TAC adequately alleges that Defendant Malik knew about Mylan's market allocation of Doxy

DR, but Defendants now argue that Plaintiffs have failed to plead Malik's scienter with respect to any other market allocation activity, or with respect to Mylan's price-fixing activity.

Tellabs teaches that scienter allegations are to be judged "holistically." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007). "[T]he overall domestic and foreign pricing scheme of an important product may perhaps be of such importance to a corporation that its officers should be presumed to know of it under the 'core operations' doctrine . . . ." *Frederick v. Mechel OAO*, 475 F. App'x 353, 357 n.6 (2d Cir. 2012). "[C]ourts since *Tellabs* have concluded that even if the plaintiff demonstrates only that an inference of scienter is at least as compelling as any nonculpable explanation . . . , the tie . . . goes to the plaintiff." *Okla. Firefighters Pension & Ret. Sys. v. Lexmark Int'l, Inc.*, 367 F. Supp. 3d 16, 39 (S.D.N.Y. 2019).

There should be no question at this point that each of the Individual Defendants, who each served either as President, CEO, CFO or Chief Accounting Officer, (TAC ¶ 579), knew or was severely reckless in not knowing that their Company was a leader of perhaps the largest cartel in history. The TAC alleges that Mylan allocated the market for, or fixed the prices of, 37 generic drugs, and Defendants concede that Plaintiffs have adequately alleged antitrust violations with respect to 19 of those drugs. The Individual Defendants were at the helm of this enterprise.

Generic drugs were Mylan's primary source of profit, and so constituted its core operations, for most of the time Mylan engaged in its price-fixing and market allocation activity. (TAC ¶¶ 45, 47 (showing EpiPen sales accounting for 27.5%-38.3% of total profits and stating "*after revenue from generics*, "[r]emaining sales come from . . . the . . . EpiPen").) Mylan's "pricing scheme" was of "such importance" to Mylan that "its officers should be presumed to know of it under the 'core operations' doctrine." *Frederick*, 475 F. App'x at 357 n.6.

These core operations allegations are certainly not the only basis for a strong inference of the Individual Defendants' scienter.[9] This Court already has sustained allegations that the Individual Defendants each knew of either Mylan's market allocation or price-fixing activity. Yet the TAC clearly alleges that the two activities often were interconnected. That the Individual Defendants somehow had compartmentalized knowledge of only one, but not both, aspects of the Company's cartel, is implausible. *See In re Health Mgmt. Inc. Sec. Litig.*, 970 F. Supp. 192, 204 (E.D.N.Y. 1997) (inventory fraud scienter supported accounts receivable fraud scienter). To attempt to parse scienter allegations for certain generic drugs when Defendants were engaged in a market-wide scheme ignores the allegations of the TAC—and common sense.

VII. PLAINTIFFS HAVE ADEQUATELY PLEADED LOSS CAUSATION FOR MAY 28, 2019

Plaintiffs have adequately pleaded that the drop in the Company's share price on May 28, 2019 caused them recoverable losses. As explained above, loss causation, "is not intended to impose a great burden on a plaintiff," as Plaintiffs need only meet Rule 8 notice pleading standards, which are met by "provid[ing] a defendant with some indication of the loss and the causal connection that the plaintiff has in mind . . . ." (MTD Op. at 35-36) (quoting *Fin. Guar. Ins. Co.*, 783 F.3d at 404); *Dura Pharm.*, 544 U.S. at 347. "[T]o establish loss causation, [plaintiffs must show that a] . . . misstatement or omission concealed *something* from the market that, when disclosed, negatively affected the value of the security." *In re Vivendi*, 838 F.3d at 261-62 (citation omitted). Given the fact-intensive nature of the loss causation inquiry, the Court has rightly "defer[red] questions about the robustness of Plaintiff's selection of corrective disclosures to a later stage of litigation, after the aid of discovery." (MTD Op. I at 35-36.)

[9] The Second Circuit has not reached the question whether a strong inference of scienter may follow directly from a "core operation" inference. *Frederick*, 475 F. App'x at 356 n.5 ("We do not reach the question whether the district court was correct in holding that a complaint cannot adequately plead scienter on the basis of the "core operations" doctrine alone."). In any event, Plaintiffs do not rely solely on the core operations inference to plead scienter.

With respect to the May 28, 2019 disclosure date, Plaintiffs have "provide[d] defendant[s] with some indication of the loss and the causal connection that the plaintiff has in mind." (*Id.*) As stated in the TAC, on May 28, 2019, UBS published a report in which it "provided details regarding the potential exposure the Company faced in the 2017 and 2019 antitrust suits by the state attorneys general." (TAC ¶ 576.) These details revealed new information about the size of the impact of the Company's misrepresentations about its anticompetitive activity on the Company's value. *Id.*; *see* Van Decl., Ex. A.

Defendants argue that the May 28, 2019 UBS report could not have served as a corrective disclosure. (Defs.' Mem. at 24.) According to Defendants, the UBS report "did not contain . . . new information" as "the facts that formed the basis of the analyst's estimates and opinions had already been publicly revealed . . . ." (*Id.*) Defendants are wrong. The May 28, 2019 UBS report was based on private discussions between UBS and the legal team responsible for the most recent complaint filed by the state attorneys general against TEVA and Mylan. *See* Van Decl., Ex. A at 1 ("We had a chance to speak with TEVA's legal team . . . . TEVA expects litigation to take several years to resolve . . . . For MYL we calculate potential litigation charges of $0.1-$2.1B"). The information from TEVA's legal team gathered by UBS in these discussions concerning Mylan's litigation exposure was not previously available publicly.[10]

VIII. CONCLUSION

Defendants' Motion should be denied for the above reasons.

[10] In any event, an analysis even of publicly available facts may constitute a corrective disclosure if that analysis goes beyond "merely a journalist's negative opinion" and sheds light on facts not previously appreciated. *See In re Signet Jewelers Ltd. Sec. Litig.*, No. 16 Civ. 6728, 2019 U.S. Dist. LEXIS 114695, at *50 (S.D.N.Y. July 10, 2019) ("As to the *Grant's* report, Defendants are incorrect that it simply published already-known information. *Grant's* reported on increasing bankruptcy figures . . . . It was not, as Defendants contend, merely a journalist's negative opinion, but an analysis of how and why Signet's underlying business was weaker than most people realized. It thus qualifies as corrective."); *see also In re Vivendi*, 838 F.3d at 263 (announcements by credit rating agency of credit downgrades and potential future credit downgrades may constitute corrective disclosures); *In re Apollo Grp., Inc. Sec. Litig.*, No. 08-16971, 2010 U.S. App. LEXIS 14478, at *2 (9th Cir. June 23, 2010) (analyst report constitutes a corrective disclosure if the "public initially failed to appreciate the significance of negative information.")

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Respectfully submitted,

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